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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,386	08/16/2007	Paul Hallenbeck	105576-0069-101	9076
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ROPES & GRAY LLP			NGUYEN, QUANG	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,386	<b>Applicant(s)</b> HALLENBECK ET AL.
	<b>Examiner</b> QUANG NGUYEN, Ph.D.	<b>Art Unit</b> 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-31 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-31 are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 

Paper No(s)/Mail Date \_\_\_\_
- 4) Interview Summary (PTO-413)
 

Paper No(s)/Mail Date \_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_

#### **DETAILED ACTION**

Claims 1-31 are pending in the present application, and they are subjected to the following species restriction.

#### ***Species Election/Restrictions***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. (a) *a replication competent adenovirus vector wherein first and second adenovirus genes under transcriptional control of TMPRSS2 TRE; (b) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a second adenovirus gene essential for replication under transcriptional control of a PSA-TRE; (c) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a second adenovirus gene essential for replication under transcriptional control of a PB-TRE; (d) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a second adenovirus gene essential for replication under transcriptional control of a hKLK2-TRE; (e) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under*

*transcriptional control of TMPRSS2 and a second adenovirus gene essential for replication under transcriptional control of a TERT-TRE; (f) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a second adenovirus gene essential for replication under transcriptional control of a E2F-TRE; (g) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication and a transgene under transcriptional control of TMPRSS2; (h) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a transgene under transcriptional control of a PSA-TRE; (i) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a transgene under transcriptional control of a PB-TRE; (j) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of hKLK2-TRE; (k) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a transgene under transcriptional control of a TERT-TRE; and (l) a replication competent adenovirus vector wherein a first adenovirus gene essential for replication under transcriptional control of TMPRSS2 and a transgene under transcriptional control of a E2F-TRE.*

**2. A single specifically named early gene recited in the Makush group of anyone of claims 8, 14 and 16.**

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

A replication competent adenovirus vector comprising a prostate specific transcriptional regulatory element (TRE) derived from the sequence upstream of the translational start codon for a TMPRSS2 gene, wherein said adenovirus vector selectively replicates in prostate cancer cells; the same replication competent adenovirus vector wherein said adenovirus has a first adenovirus gene essential for replication under transcriptional control of said TMPRSS2 TRE and said first adenovirus gene essential for replication is an early gene selected from the group consisting of E1a, E1b and E4.

The following claim(s) are generic: at least claims 5-8.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the above replication competent adenovirus vectors and/or recited early genes is different structurally as well as having different properties one from the others. Each different replication competent adenovirus and/or early gene can be considered to be a "special technical feature" and therefore the above listed species lack the same or corresponding special technical features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.**

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN/  
Primary Examiner, Art Unit 1633